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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,654	07/10/2006	Tetsuya Okano	0425-1218PUS1	5662
2292 7590 04/29/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER FISHER, ABIGAIL L				
ART UNIT 1616		PAPER NUMBER		
NOTIFICATION DATE 04/29/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/551,654

Applicant(s)

OKANO ET AL.

Examiner

ABIGAIL FISHER

Art Unit

1616

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-14,16-19 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12-14,16-19 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2009 has been entered.

Receipt of Amendments/Remarks filed on November 19 2009 and Amendments/Remarks and Declaration under Rule 132 filed on January 4 2010 is acknowledged. Claims 1-9, 11, 15 and 19-21 were/stand cancelled. Claims 10 and 13-14 were amended. Claims 22-24 were added. Claims **10, 12-14, 16-19 and 22-24** are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-14, 16-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura et al. (US Patent No. 5827447, cited in the Office action mailed on 3/18/09) in view of Kobayashi et al. (US Patent No. 5869440, cited in the Office action mailed on 3/18/09).

Applicant Claims

The instant application claims a sterilizer composition having a pH value of 1 to 5 at 25 °C and comprising water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group with (B2) hydrogen peroxide in an (A)/(B1) molar ratio of 1/10 to 20/1 in water at pH 8 to 12. The instant application claims a method of sterilizing a material comprising contacting the material with the solution above. The instant application claims a process for producing a sterilizer composition comprising reacting (A) with (B1) in an (A)/(B1) molar ratio of 1/10 to 20/1 in water at pH 8 to 12 then adjusting the reaction system to pH 1 to 5.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tamura et al. is directed to a transparent liquid bleaching agent having a transparent appearance and excellent storage stability and bleaching power (abstract). The composition comprises hydrogen peroxide, a surfactant, and a bleach activator capable of yielding an organic peracid with reacted with hydrogen peroxide (column 3, lines 11-15). The hydrogen peroxide is incorporated in an amount of 0.3 to 30% by weight into the composition (column 3 lines 44-46). The bleach activator utilized to yield and organic peroxide when reacted with hydrogen peroxide includes triacetin, a fatty acid anhydride having 2 to 18 carbon atoms, and sodium alkanoyloxybenzenesulfonate (column 6, lines 50-57). Surfactant and bleach activator are incorporated in total amount of (surfactant plus bleach activator) 0.1 to 50% by weight of the composition. The ratio of surfactant to bleach activator is 50:1 to 1:1 (column 8, lines 60-67).

Exemplified ratios of bleach activator to hydrogen peroxide are 2:5 and 1:5 (table 1 and 2). Exemplified methods of formation teach adding surfactants, bleach activators, hydrogen peroxide. The pH value of each composition was adjusted to 2 with **sulfuric acid**. Commercially available products which showed little storage stability had a pH of 10.2 (column 13, lines 1-2 and table 1). The exemplified compositions all comprise water.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Tamura et al. do not specify a pH of 8 to 12 or 9 to 11 prior to acidification.
Tamura et al. do not specify maintaining at a pH of 8 to 12 for 1 to 120 minutes.
Tamura et al. do not teach a method of sterilizing. However, these deficiencies are cured by Kobayashi et al.

Kobayashi et al. is directed to peroxide activation. It is taught that for domestic or industrial use, it is preferable to use hydrogen peroxide of concentrations not higher than 6% in order not to be designated as a powerful drug. It is taught that to stabilize a hydrogen peroxide solution, the pH of the solution is adjusted not higher than 9 (column 2, lines 25-38). It is taught that bleach concentrations lower than 0.3 wt. %, the bleaching effect is not sufficient (column 3, lines 26-27). It is taught that an alkaline pH is utilized to make hydrogen peroxide decompose so as to be used as an agent for cleaning, bleaching, sterilizing, deodorizing etc. in domestic or industrial use (column 3, lines 17-21). As shown in comparative example 4, when utilizing triacetin as the bleach activator, when the pH is maintained at 10.9 there is a 80% reduction of the bleaching rate at 50 °C (table 2, example 4).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Tamura et al. and Kobayashi et al. and utilize a pH greater than 9 in order to decompose the hydrogen peroxide for use as a sterilizer but then decrease the pH in order to stabilize the hydrogen peroxide solution for long term storage. One of ordinary skill in the art would have been motivated to initially have the pH of a peracid generating solution be greater than 8 as Kobayashi et al. teach that this is the pH utilized to decompose the hydrogen peroxide so it can be utilized in domestic or industrial use. Then one of ordinary skill in the art would have been motivated to decrease the pH to that of around 2 as Tamura et al. teach that this is a pH that provides long-term shelf stability and Kobayashi et al. teach that triacetin and hydrogen peroxide containing solutions lose about 80% of their efficacy after 5 days at a pH of around 11. While Tamura et al. do not specify the pH of the composition initially, it must necessarily be higher than 2 because the pH is adjusted to 2 with sulfuric acid. Therefore, based on these teachings it would have been obvious to one of ordinary skill in the art to initially have the pH of the bleaching composition be greater than 8 and then decrease the pH to that of about 2.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Tamura et al. and Kobayashi et al. and utilize the bleaching composition in a method of sterilization. One of ordinary skill in the art would have been motivated to utilize the bleaching composition in a method of

sterilization as this type of method is taught as a suitable use for a bleaching composition by Kobayashi et al.

Regarding the structure of product (A) (specifically corresponding to claims 1, 7-8, 10, 13-14 and 17-18), the instant specification indicates compounds fitting this particular structure include triacetin. Triacetin is a specific type of bleach activator taught by Tamura et al.

Regarding the claim amount of hydrogen peroxide, Tamura et al. teach amounts that overlap that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Regarding the claimed reaction time of the hydrogen peroxide and triacetin at pH greater than 8, it would have been obvious to one of ordinary skill in the art to manipulate the reaction time in order to optimize the decomposition product while maintaining bleaching efficacy. Kobayashi et al. teach that a triacetin and hydrogen peroxide solution losses about 80% efficacy after 5 days and teaches that some decomposition of the hydrogen peroxide is necessary in order for the agent to be utilized. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the reaction time in order to what time produces the optimal bleaching effect. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments/Declaration under Rule 132

The declaration under 37 CFR 1.132 filed 1/4/10 is insufficient to overcome the rejection of claims **10, 12-14, 16-19 and 22-24** based upon **Tamura et al. in view of Kobayashi et al.** as set forth in the last Office action because: the declaration is not commensurate in scope nor is it a true side by side comparison. Firstly, Tamura et al. teach that the pH of each composition was adjusted to 2 with sulfuric acid (column 12). However, the data presented in table 2 uses "sulfonic acid" which is a completely different acid than that used by Tamura et al. While phosphoric acid and sulfuric acid are mineral acids, sulfonic acid is not (it is an organic acid). Therefore, the acid used for the Tamura et al. references does not represent a true side by side comparison. Secondly, the amounts of components A and B of the instant invention and that of examples of Tamura et al. are not the same. In order to establish a true side by side comparison (especially if applicants are attempting to show the novelty and unobviousness of their claimed method of making) then the amounts of ingredients used in comparisons should be the same for both the example(s) of instant invention

and comparatives. Finally, the data presented in Table A is only for one particular data point. If assuming arguendo that the data presented in Table A was a true side by side comparison then that data presented would only be persuasive for that particular point. Applicants are claiming a range of components A and B. Therefore, the data presented must be commensurate in scope with the claims and applicants should present a representative number of examples to establish unexpectedness of the claimed range. Since the art already recognizes that organic peracids are known to be utilized in sterilization, there already is an expectation that use of the organic peracid would be beneficial in sterilization. Therefore, applicants would need to establish the purported unexpected results over the claimed ratios thereby establishing that the difference in the number of remaining microorganisms is not due to the difference in the concentration of components A and B.

Applicants argue that the declaration shows strong evidence that the cited references do not produce the results of the present invention.

Applicants' arguments filed January 4 2010 have been fully considered but they are not persuasive.

As indicated above, the declaration is insufficient as it fails to show a true side by side comparison and is not commensurate in scope. Tamura et al. teach formation of a liquid bleaching composition comprising hydrogen peroxide and a bleach activator. The final pH is the same as the final pH instantly claimed. Tamura et al. does not specify the pH prior to adjustment. Since Tamura et al. teach that the formulation is a bleaching

formulation and Kobayashi et al. teach that these compositions are known to utilized for sterilizing, there is a reasonable expectation that these compositions are effective in sterilizing materials.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher

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Examiner

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AF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616